**Suprachoroidal Delivery of Pharmacologic Agents**

**Description**

Delivery of pharmacologic agents to the suprachoroidal space is being investigated for treatment of posterior eye segment diseases.

**Related Policies**

- Photodynamic Therapy for Subfoveal Choroidal Neovascularization
- Epiretinal Radiation Therapy

**Policy**

Suprachoroidal delivery of a pharmacologic agent is considered **investigational**.

**Policy Guidelines**

From 2008 through 2013, there was a category III CPT code specific to suprachoroidal delivery of pharmacologic agents:

- **0186T**: Suprachoroidal delivery of pharmacologic agent (does not include supply of medication)

The category III code was deleted on 12/31/13 and CPT directs users to use the following code:

- **67299**: Unlisted procedure, posterior segment

**Benefit Application**

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.
Rationale

Background
The structure of the eye is classified under 2 subheadings: (1) anterior segment and (2) posterior segment. The anterior segment consists of the front one-third of the eye and includes the pupil, cornea, iris, ciliary body, aqueous humor, and lens; the posterior segment consists of the back two-thirds of the eye and includes the vitreous humor, retina, choroid, macula, and optic nerve. Posterior segment ocular diseases (e.g., age-related macular degeneration, diabetic neuropathy) are the most prevalent causes of visual impairment. The following is a list of the various routes for ocular drug administration:

- Invasive drug administration to intraocular cavities
  - Suprachoroidal injections
  - Intravitreal surgery
  - Intravitreal injections
  - Intracameral surgery
  - Intracameral injections
  - Subretinal injection

- Invasive periocular and scleral modes of drug administration
  - Intrascleral surgery
  - Episcleral surgery
  - Periocular injections
  - Subconjuctival injections
  - Transscleral diffusion from controlled release systems

- Noninvasive methods
  - Topical administration on the eye

- Systemic administration
  - Intravenous infusion and injection
  - Oral

Many ocular diseases are treated with either topical or systemic medications. Topical application has remained the most preferred delivery route due to ease of administration. Topical application is useful in the treatment of disorders affecting the anterior segment of the eye. Although topical and systemic routes are convenient, lack of bioavailability and failure to deliver therapeutic levels of drugs to the retina has prompted vision scientists to continue to explore alternative routes of administration.

One potential advantage of suprachoroidal injection would be the ability to minimize systemic adverse effects while delivering higher local tissue levels of drugs. This proposed benefit assumes that high local levels lead to improved outcomes. Weighed against this potential benefit is the risk of localized tissue damage from the microcannula. A microcannula system combines a drug delivery channel with a fiberoptic light source for localization of the cannula tip. This technique is being investigated for the treatment of subchoroidal neovascularization related to diseases of the retina.
Regulatory Status

The iTRACK™ (iScience Interventional), which is a flexible microcannula designed to allow atraumatic cannulation of spaces in the eye for infusion and aspiration of fluids during surgery, received 510(k) marketing clearance from the U.S. Food and Drug Administration. The microcannula incorporates an optical fiber to allow transmission of light to the microcannula tip for surgical illumination and guidance. The microcannula “is indicated for fluid infusion and aspiration, as well as illumination, during surgery.”(1)

One 2007 review discussed industry-funded tests of the suprachoroidal injection technique in pig eyes.(2) Triamcinolone (3 mg) was found to remain at detectable levels in the posterior tissues of the pig eye for up to 120 days. Adverse events included infection (2 of 94), scleral ectasia (4 of 94), choroidal blood flow abnormalities (4 of 94), and inflammation (6 of 94). Some cannula tip designs resulted in snag lesions in the pigment epithelium, and the suprachoroidal space was found to separate from the sclera following injection of sodium hyaluronate but returned to a normal position after 1 month. Clinical trials in humans were reported to be ongoing.

A 2008 review by Del Amo and Urtti discussed the emerging methods of ocular drug delivery, which include polymeric-controlled release injections and implants; nanoparticulates; microencapsulated cells; iontophoresis; and gene therapy.(3) The authors note the biggest drug delivery challenge is to develop effective methods for posterior segment therapies that would also be applicable for outpatient use.

Periodic literature has identified 2 small studies from the same group of investigators. One was a prospective case series (2012) that used a microcatheter (iTRACK) for suprachoroidal drug delivery for the treatment of advanced, chronic macular edema with large subfoveal hard exudates in 6 eyes of 6 patients.(4) The subfoveal hard exudates were reported to be almost completely resolved at 1 to 2 months following a single suprachoroidal infusion of bevacizumab and triamcinolone, with no surgical or postoperative complications.

In 2012, these investigators also published an industry-sponsored retrospective analysis of 21 eyes of 21 patients with choroidal neovascularization secondary to age-related macular degeneration that were treated with bevacizumab and triamcinolone using the iTRACK microcatheter.(5) Patients were included in the analysis if they had been unresponsive to at least 3 prior treatments including thermal laser photocoagulation, photodynamic therapy, or intravitreal injections of pegaptanib, bevacizumab, or ranibizumab. Best corrected visual acuity did not improve significantly from baseline through the 6-month follow-up (0.98 logMAR [minimum angle of resolution] at baseline, 0.92 logMAR at 1 month and 0.93 logMAR at 6 months; lower scores indicate improvement). There was a significant decrease in central foveal thickness (407.2 µm at baseline to 333.3 µm at 1 month). There was no visible evidence of retinal or choroidal tissue trauma in this safety and feasibility study.

Summary

Controlled trials are needed to evaluate the safety and efficacy of suprachoroidal drug administration compared to the standard of care. Evidence to date consists of 2 small case series from the same group of investigators in Europe. Current evidence is insufficient to determine whether suprachoroidal delivery of pharmacologic agents improves the net health outcome. Thus, this procedure is considered investigational.
Medical Policy

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

References


Documentation Required for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

IE

The following services are considered investigational and therefore not covered for any indication.

<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>0186T</td>
<td>Suprachoroidal delivery of pharmacologic agent (does not include supply of medication)</td>
</tr>
<tr>
<td>HCPC</td>
<td>J2503</td>
<td>Injection, pegaptanib sodium, 0.3 mg</td>
</tr>
<tr>
<td></td>
<td>J2778</td>
<td>Injection, ranibizumab, 0.1 mg</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
Medical Policy

For dates of service on or after 10/01/2015

<table>
<thead>
<tr>
<th>ICD-10 Procedure</th>
<th>Administration, physiological systems and anatomical regions, eye, percutaneous, code list for various agent types</th>
</tr>
</thead>
<tbody>
<tr>
<td>3E0C305, 3E0C30M</td>
<td></td>
</tr>
<tr>
<td>3E0C328, 3E0C329</td>
<td></td>
</tr>
<tr>
<td>3E0C33Z, 3E0C3BZ</td>
<td></td>
</tr>
<tr>
<td>3E0C3HZ, 3E0C3NZ</td>
<td></td>
</tr>
<tr>
<td>3E0C3TZ</td>
<td></td>
</tr>
</tbody>
</table>

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>10/31/2014</td>
<td>BCBSA medical policy adoption</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**Investigational/Experimental:** A treatment, procedure or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a Split Evaluation, where a treatment, procedure or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements

This service (or procedure) is considered medically necessary in certain instances and investigational in others (refer to policy for details).

For instances when the indication is medically necessary, clinical evidence is required to determine medical necessity.
For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.